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I further certify that the above application is now proceeding in the name of CAREY TASCA PTY LTD pursuant to the provisions of Section 113 of the Patents Act 1990.

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Twenty-first day of November 2003

J. K + C.

JANENE PEISKER
TEAM LEADER EXAMINATION
SUPPORT AND SALES

**AUSTRALIA**
**Patents Act 1990**

# PROVISIONAL SPECIFICATION

Invention Title: METHOD OF SURGICAL REPAIR

Applicant: MARCUS PATRICK CAREY

The invention is described in the following statement:

# METHOD OF SURGICAL REPAIR OF VAGINA DAMAGED BY PELVIC ORGAN PROLAPSE AND PROSTHETIC MATERIALS SUITABLE FOR USE THEREIN

This invention relates to a method for the surgical repair of a vaginal wall damaged by the prolapse of any one or more of the pelvic organs, various prosthetic materials useful in such surgery and to kits suitable for use by surgeons when treating women suffering from pelvic organ prolapse.

## Background of the Invention

In Australia almost one in four women undergo surgery for pelvic organ prolapse. In many other countries the rates are higher. Pelvic organ prolapse generally involves the descent of the uterus, the bladder or the rectum along the vagina towards (or in extreme cases protruding out of) the introitus. Women of advancing years or those that have borne several children are more frequent sufferers of pelvic organ prolapse.

Traditional vaginal surgery is associated with a high failure rate. It is between 30-40%. Complex and elaborate abdominal, vaginal and laparoscopic procedures such as abdominal sacral colpopexy, transvaginal sacrospinous ligament fixation and laparoscopic sacral colpopexy have been developed to reduce the risk of prolapse recurrence. Unfortunately these procedures require a high level of surgical expertise and are only available to a small number of specialist practitioners and therefore to a small number of patients.

More recently there has been a trend towards the use of reinforcing materials to support a vaginal wall damaged by prolapse. Prosthetic materials such as donor fascia lata, pig dermis and various types of synthetic mesh have been utilized with mixed success. These materials are generally positioned under the vaginal wall or walls and sutured into position. The applicant has recognized that the synthetic meshes currently in use are far from ideal as they have been designed principally for the treatment of anterior abdominal wall herniation and are generally too heavy for the treatment of genital prolapse. Some of the meshes in current use are associated with long term problems which include pain with sexual intercourse, erosion of the mesh into the lumen of the vagina (this requires surgery to remedy) and shrinkage of the mesh.

It is an object of the present invention to provide a simplified surgical procedure suitable for treatment of different forms of pelvic organ prolapse which has a failure rate lower than for current methods. It is a further object to

provide an improved prosthetic material suitable for vaginal repair in the treatment of pelvic organ prolapse.

Summary of the Invention

In accordance with the first aspect of the present invention there is provided a method for repairing a vaginal wall which has been damaged by one or more prolapsed pelvic organs, said method including:

(a) mobilising the vaginal epithelium off the underlying fascia of at least a portion of the damaged vaginal wall;

(b) positioning a prosthetic material over the exposed fascia;

(c) re-fixing the vaginal epithelium over the prosthetic material and the fascia; and thereafter

(d) locating an intra-vaginal splint into the vagina.

In this description of the method of the invention and elsewhere in this specification the phrase "intra-vaginal splint" means any device sized to be located in the lumen of the vagina and which, once located in the lumen of the vagina, will reduce the mobility of the vaginal walls.

Preferably the prosthetic material once positioned over the exposed fascia is attached to the fascia. Such attachment is usually achieved by sutures, but other methods may be utilised such as by the application of adhesives or surgical staples.

In some minor cases of prolapse, repair is required to only one of the vaginal walls. However, in most cases of prolapse, repair is required to the anterior and posterior walls of the vagina. In such cases it is not important whether the anterior or posterior wall is repaired first, although it is usually convenient to repair the anterior wall first. Thus, in accordance with the present invention, if both vaginal walls are to be repaired, an intra-vaginal splint is located in the vagina after prosthetic material has been positioned over the fascias of both the anterior and posterior vaginal walls.

Therefore, in the case where both the anterior and posterior vaginal walls are being repaired the preferred method of the invention includes the following steps:

(a) mobilising the vaginal epithelium off the underlying fascia of at least a portion of the anterior vaginal wall;

(b) positioning a first prosthetic material over the exposed fascia of the anterior vaginal wall;

(c) re-fixing the vaginal epithelium over the said first prosthetic material and the fascia of the anterior vaginal wall;

(d) mobilising the vaginal epithelium off the underlying fascia of at least a portion of the posterior vaginal wall;

(e) positioning a second prosthetic material over the exposed fascia of the posterior vaginal wall;

(f) re-fixing the vaginal epithelium over the said second prosthetic material and the fascia of the posterior vaginal wall; and thereafter

(g) locating an intra-vaginal splint into the vagina.

Preferably, the surgery is performed vaginally.

In most cases the intra-vaginal splint should be removed after the prosthetic material has become incorporated into the vaginal wall tissue. Preferably the intra-vaginal splint remains in position in the vagina for at least 3 weeks following surgery. Most preferably the intra-vaginal splint is removed between 4 to 6 weeks following surgery.

The vaginal epithelium covering the anterior wall is preferably mobilised by incision and lateral dissection - most desirably dissection is carried out to the arcus tendineous facia pelvie on both sides. The pubo-cervical fascia of the anterior wall may be plicated with sutures before the first prosthetic material is positioned over the exposed fascia.

Likewise, when repairing the posterior vaginal wall the underlying fascia (the recto-vaginal septum fascia) may be plicated. The vaginal epithelium covering the posterior wall is preferably mobilised by incision and dissection – laterally to the levator ani muscles on each side and in the upper part of the vagina, in a lateral and cranial direction through the rectal pillars on both sides towards the sacrospinous ligaments on each side.

The surgical method described above can be employed with any of the conventional prosthetic materials currently in use for the treatment of pelvic organ prolapse. The use of an intra-vaginal splint following the positioning of prosthetic materials substantially reduces the mobility of the vaginal walls,

uterus, bladder base and anterior rectal wall resulting in improved wound healing and a reduced rate of surgical failure.

It is preferred however, that the method of the present invention be carried out with a synthetic mesh.

In accordance with a further aspect of the present invention there is provided a flexible synthetic mesh for use in the repair of a vaginal wall damaged by the prolapse of one or more pelvic organs said synthetic mesh including a plurality of open pores bounded by strands made of non-woven polymeric material, wherein the junctions between the respective strands are without open interstices and wherein a majority of the open pores of the mesh have an area of less than 15 $mm^2$.

Preferably all of the pores of the mesh have an area of less than 15 $mm^2$. Most preferably, the pore size of a majority of the pores of the mesh have an area of less than 10$mm^2$.

The mesh may be of any suitable shape but generally will incorporate a central body portion and two longitudinal side portions. In the most preferred embodiments the pore size in the central body portion of the mesh is greater than the pore size in the longitudinal side portions. Most preferably the area of each of the pores in the body of the mesh are less than 10 $mm^2$ and the area of each of the pores in the side portions of the mesh will be less than 5 $mm^2$. It is also preferred that the side portions have a width of at least 3 mm.

It is highly desirable that the mesh be light and very flexible. Preferably the mesh has a weight of less than 0.0080 $g/cm^2$. Most preferably its weight is between 0.0020 and 0.0050 $g/cm^2$. Any flexible biocompatible polymeric material may be utilised. The preferred polymeric material is polypropylene and the polypropylene fibres are preferably monofilament fibres.

The mesh of the present invention does not include any open interstices at the junctions between the respective strands. This is important to minimise bacterial growth in or around the mesh after it has been positioned under the virginal wall. Thus the mesh will not be woven but instead can be formed by stamping the profile out of a sheet of the polymeric material being used or alternatively, adjacent strands may be connected in a way which does not produce open interstices at the junctions between the respective strands. Most conveniently this is achieved by bonding or welding.

The synthetic mesh of the present invention may be produced in a substantially oval shape for the repair of the anterior vaginal wall and may be produced with two extension arms extending from both side portions of the mesh for repair of the posterior vaginal wall.

When using a mesh shaped for repair of the posterior vaginal wall incorporating extension arms, the mesh is placed over the recto-vaginal septum fascia with each extension arm placed into the tunnel extending from the posterior vaginal wall dissection to the sacrospinous ligament. The mesh is positioned over the fascia and the posterior vaginal wall epithelium is then closed and re-fixed over the mesh to complete the repair. The prosthetic material, whether it be a preferred synthetic mesh described above or some other suitable material is desirably attached to the respective fascia by using sutures attaching the sides of the prosthetic material to the fascia wall.

Once the vaginal wall or walls have been repaired an intra-vaginal splint is located in the vagina and preferably sutured into position to prevent extrusion. Alternatively the intra-vaginal splint may include lateral spurs. Preferably the intra-vaginal splint is a semi-rigid device and most preferably it is made of a flexible medical grade silicone. As the vagina does not have a universal shape and size it is preferred that the surgeon have available to him at least three differently sized splints so that a splint may be selected which will be appropriate for the patient being treated. Most desirably, a sizing kit will be utilized allowing the surgeon to choose the appropriately sized splint. The sizing kit should comprise at least three differently sized model splints preferably made of medical grade silicone, so that the model splints may be sterilized allowing multiple use. The surgeon will choose the particular sized intra-vaginal splint that matches the corresponding model intra-vaginal splint from the sizing kit, preferably choosing the splint that most comfortably fits into the vagina following the repair whilst contacting both lateral vaginal walls and the superior aspect of the vagina.

In one form, the intra-vaginal splint of the present invention includes two longitudinally extending side arms which are joined at their bottom ends by a transverse member and which are joined at their top ends by a curved connecting member having a central portion which is substantially "U" shaped, wherein the base of the "U" shaped central portion is located between the

longitudinal side arms. The "U" shaped central portion is provided to accommodate the cervix in women who have not had a prior hysterectomy or do not have a hysterectomy at the time of prolapse surgery.

Preferably the intra-vaginal splint is resilient and bendable about its longitudinal axis so that on application of a bending force the two longitudinally extending side members may be brought into close proximity so that they are substantially side by side and whereupon release of the bending force will result in the longitudinally extending side members moving away from each other.

An interior part of the splint may be closed by a membrane. In one embodiment the closed membrane is inflatable so that inflation of the membrane once the intra-vaginal splint is in place will permit the surgeon to tamponade the vagina to prevent and/or control post operative bleeding. This may avoid the need to use a vaginal pack. However, if the surgeon wishes to place a vaginal pack this can be placed around the splint and a urethral catheter can also be placed.

The intra-vaginal splint is used to improve wound healing and strength, reduce movement and displacement of the mesh whilst it is becoming incorporated into the vaginal fascial tissues and to avoid the need to use supporting sutures into structures such as the sacrospinous ligament or high onto the uterosacral ligaments. Such sutures are often difficult to place and are associated with significant patient morbidity.

In a further aspect of the present invention there is provided a kit suitable for use by surgeons when surgically treating women suffering from pelvic organ prolapse said kit including at least one piece of a flexible synthetic mesh having a plurality of open pores bounded by strands made of non-woven polymeric material in which junctions between the respective strands are without open interstices and wherein a majority of the open pores of the mesh have an area of 15mm$^2$ and a range of three or more differently sized intra-vaginal splints. The flexible synthetic mesh may be provided in a sheet so that appropriately shaped segments can be cut out of the sheet for use in the surgical methods of the invention. Preferably the kit includes a selection of pre-shaped meshes for treatment of both the anterior and posterior vaginal walls in the preferred shapes, pore sizes and configurations as described above. The kit may also

include written directions for the use of the components of the kit in accordance with the surgical methods hereinbefore described.

The present invention is hereafter further described by reference to preferred embodiments with reference to the drawings in which:-

Figure 1 is a schematic representation of the anterior vaginal wall showing incision into the vaginal epithelium;

Figure 2 is a schematic representation of the anterior vaginal wall after mobilisation of the epithelium;

Figure 3 is a schematic representation of the anterior vaginal wall with mesh positioned over the exposed fascia and sutured into place;

Figure 4 is a schematic representation of the anterior vaginal wall after the epithelium has been refixed and closed with sutures;

Figure 5 is a schematic representation of the posterior vaginal wall showing incision into the epithelium;

Figure 6 is a schematic representation of the posterior vaginal wall after mobilisation of the vaginal epithelium;

Figure 7 is a schematic representation of the posterior vaginal wall with mesh positioned over the exposed fascia and sutured into place;

Figure 8 is a schematic representation of the posterior vaginal wall after the epithelium has been refixed and closed with sutures;

Figure 9 is a schematic representation of a preferred shape and configuration of a mesh of the present invention for repair of the posterior vaginal wall;

Figure 10 is a schematic representation of a preferred shape and configuration of a mesh of the present invention for repair of the anterior vaginal wall;

Figure 11 is a schematic representation of a preferred intra-vaginal splint (front view);

Figure 12 is a schematic representation of the preferred intra-vaginal splint of the present invention with inflated membrane;

Figure 13 is a schematic representation of the intra-vaginal splint shown in Figure 12 from the side with the membrane inflated;

Figure 14 is a schematic representation of the intra-vaginal splint shown in Figure 11 showing the preferred change in angular disposition along the length of the longitudinally extending side members; and

Figure 15 is a schematic representation of a kit of six differently sized model intra-vaginal splints.

Turning to Figure 1 there is shown the open vagina (1) and anterior vaginal wall (2). The vaginal wall (2) is covered by an epithelium layer (3). An incision into the vaginal epithelium is shown in Figure 1. Once the initial incision along the vaginal epithelium layer (3) has been carried out the epithelium (3) is peeled and held away from the fascia (6) as shown in Figure 2. This lateral dissection is carried out to the arcus tendinous fascia pelvie on both sides. Mesh (7) is then positioned over the defect (4) of the exposed fascia (6) as shown in Figures 2 and 3. The mesh (7) shown in Figure 3 can be seen in greater detail in Figure 10. The mesh (7) is substantially oval in shape having a central body portion (8) and longitudinal side portions(9 and 10). For most cases a mesh having a length of about 50 mm and a width of between about 30-40mm will suffice. However, it will be appreciated that the mesh size will depend largely on the dimensions of the vaginal wall being repaired. The mesh shown in Figures 3 and 10 is made from polypropylene. In the central body portion (8) of the mesh (7) the area of each of the pores is approximately $9mm^2$ (3 mm x 3 mm). The side portions (9 and 10) have a pore size of approximately $3mm^2$ (1 mm x 3 mm). Side portions (9 and 10) are approximately 5 mm in width. The mesh is made from monofilament polypropylene and is a bonded or welded mesh having a weight of about 0.003 $g/cm^2$. Once the mesh (7) has been positioned over the fascia (6) of the anterior vaginal wall (2) it is attached onto the fascia (6) by sutures (11). Excess vaginal epithelium is then trimmed and the anterior vaginal wall is closed by sutures (12) as shown in Figure 4.

Repair of the posterior vaginal wall is shown in Figures 5 to 8. In Figure 5 posterior vaginal wall (13) is shown with the epithelium (14) of the posterior vaginal wall in place. A longitudinal incision is performed in order to mobilise the epithelium (14) off the underlying fascia (15) as shown in Figure 5. The defect 15a in fascia 15 is illustrated in Figure 6. Dissection is carried out laterally to the levator ani muscles on each side. This is also depicted in Figure 6. In the upper part of the vagina, dissection is continued in a lateral and cranial

direction through the rectal pillars on both sides towards the sacrospinous ligaments on each side. This forms bilateral tunnels from the posterior vaginal wall dissection to each sacrospinous ligament. The fascia of the recto-vaginal septum is plicated (not shown). The pre-shaped mesh (16) designed for the posterior vaginal wall repair is shown in Figures 7 and 9. It is placed over the recto-vaginal septum facia (15) with each extension arm (17,18) placed into the tunnel extending from the posterior vaginal wall dissection to the sacrospinous ligament. Turning to Figure 9 it can be seen that the pre-shaped mesh (16) designed for the posterior vaginal wall (13) repair has a central body portion 19 and longitudinal side portions 20 and 21. The width of this mesh varies from about 3 cm at the base to 11 cm at the top. The width at the top (22) of the central body portion(19) of the mesh (16) is about 6 cm. The midline length of the mesh (16) is about 7 cm and the length of each extension arm (17,18) is about 5 cm with a width of about 1.5 cm. Again the mesh (16) is made from monofilament polypropylene and is a bonded or welded mesh having a weight of about 0.003 g/cm$^2$. The area of the pore size of each of the pores of the central body portion (19) of the mesh is approximately 9mm$^2$ (3 x 3 mm) and at the longitudinal side portions (20,21) approximately 3mm$^2$ (1 x 3 mm).

Once the mesh (16) has been positioned over the fascia, it is anchored into place by sutures (23) as shown in Figure 7. Excess posterior vaginal wall epithelium (14) is trimmed and the vaginal epithelium (14) is refixed over mesh (16) as shown in Figure 8.

At this point the intra-vaginal splint sizing kit shown in Figure 15 is used. The surgeon selects from the kit the appropriately sized splint. Once the correct size for the intra-vaginal splint has been determined by using the model splints from the kit, the intra-vaginal splint is inserted into the vagina and sutured into position to prevent extrusion.

The preferred intra-vaginal splint is shown in Figures 11 to 14. It includes longitudinally extending side members 24 and 25, transverse member 26 and curved connecting member 27. The central portion (28) of connecting member (27) is substantially "U" shaped. The base (29) of "U" shaped central portion (28) is located between longitudinal side arms(24,25). Preferably the base (30) of the splint (that section extending about 20 mm from the transverse member (26) is inclined at about 10° from the remaining portion 31 of the splint. This is

best seen in Figure 14. The central part of the splint is closed by an inflatable silicon membrane 32. Inflation of the membrane with fluid is shown in Figure 12(perspective view) and 13 (side view).

The intra-vaginal splint is preferably retained in the vagina for a period of four to six weeks. Once this period has elapsed the splint can be removed by which time the synthetic mesh should have become incorporated into the tissue of each of the respective vaginal walls.

The present invention involves a simplified procedure for the treatment of pelvic organ prolapse and vaginal repair. The meshes described are significantly better suited for vaginal surgery as compared with meshes available in the past and in current use and the surgical method enables surgeons to treat prolapse without using complex abdominal, vaginal or laparoscopic procedures.

Dated: 15 November, 2002

PHILLIPS ORMONDE & FITZPATRICK
Patent Attorneys for:
MARCUS PATRICK CAREY

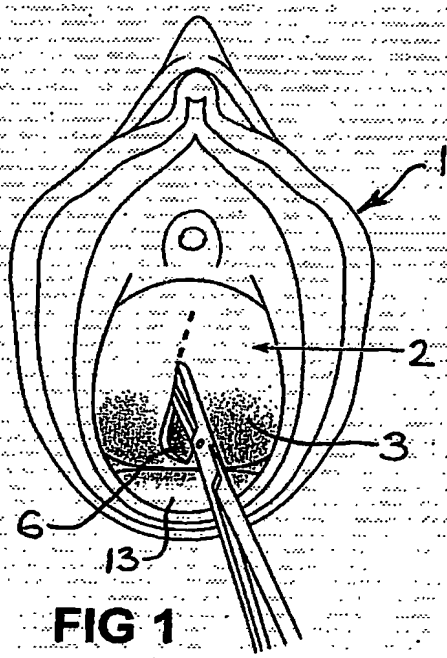


FIG 1

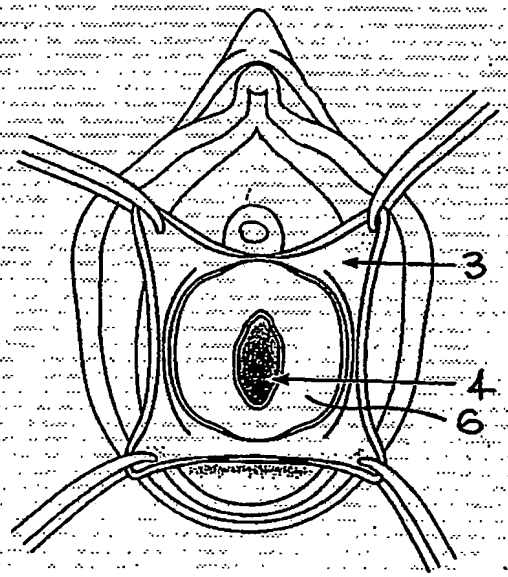


FIG 2

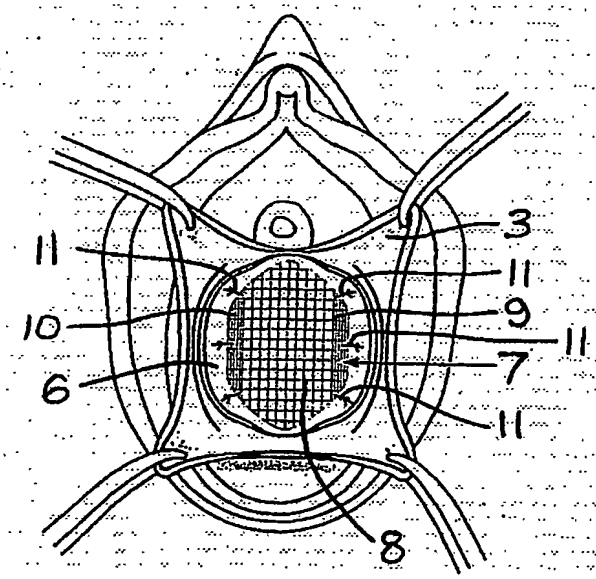


FIG 3

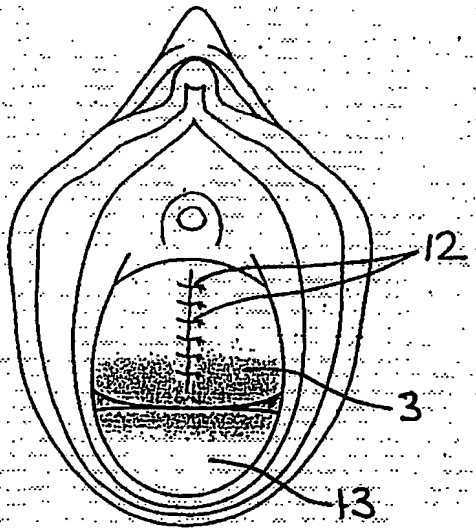


FIG 4

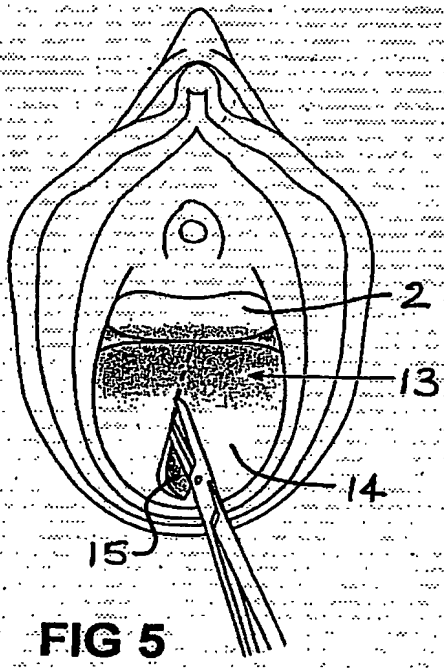


FIG 5

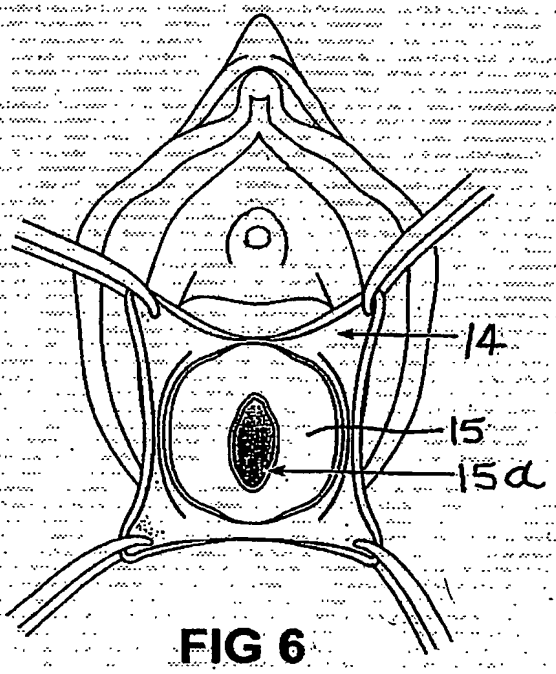


FIG 6

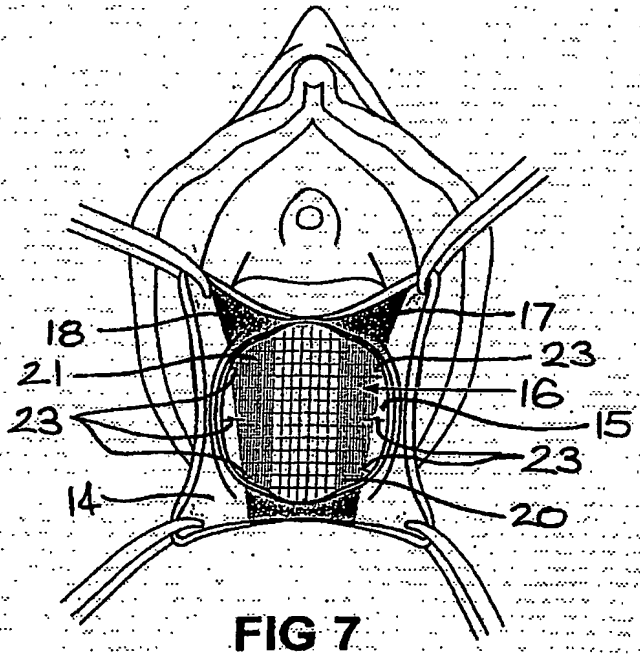


FIG 7

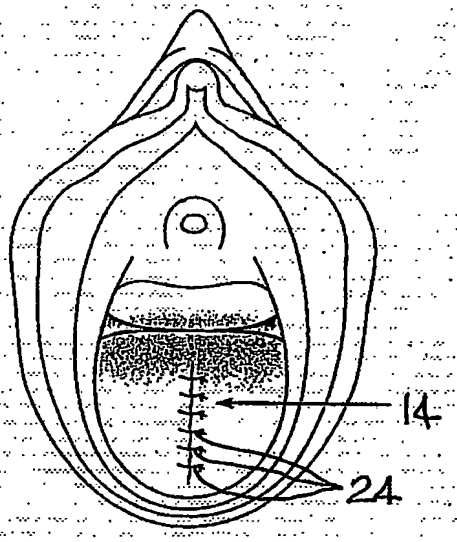


FIG 8

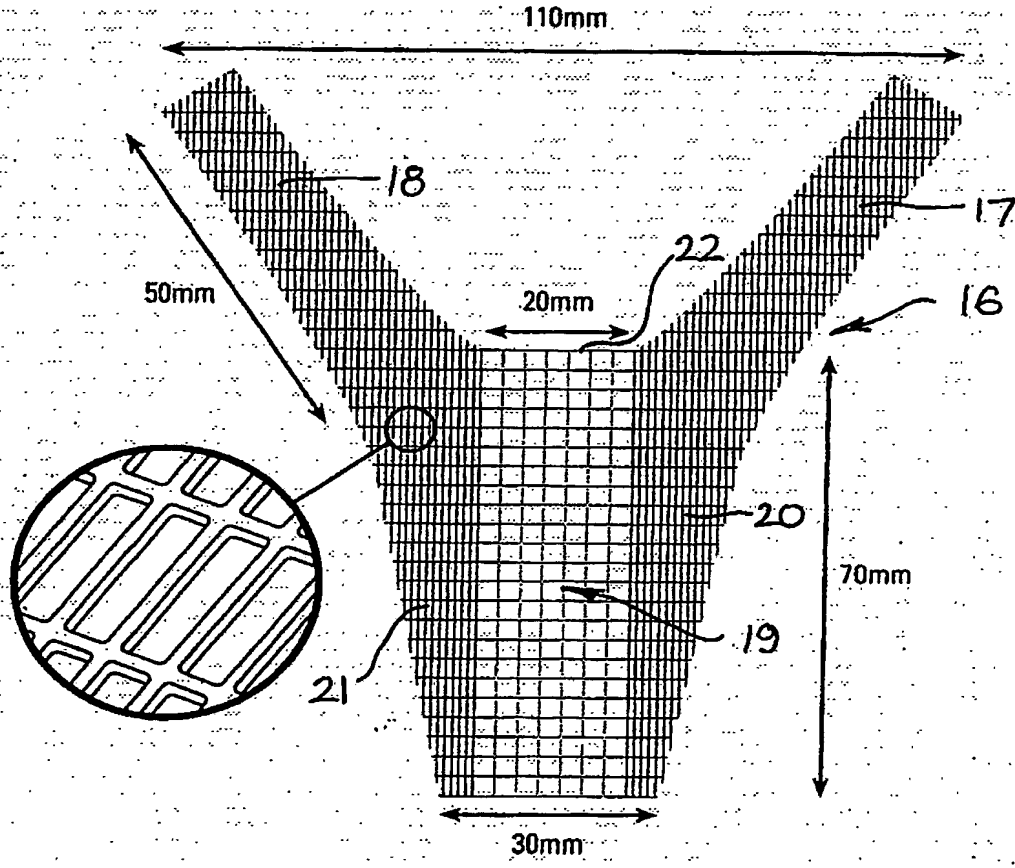


FIG 9

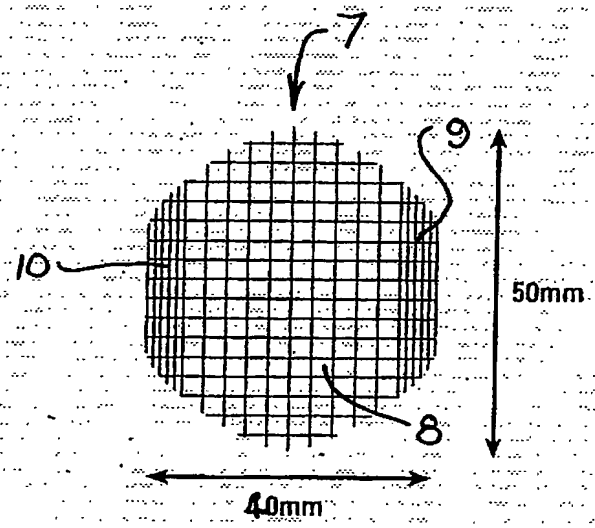


FIG 10

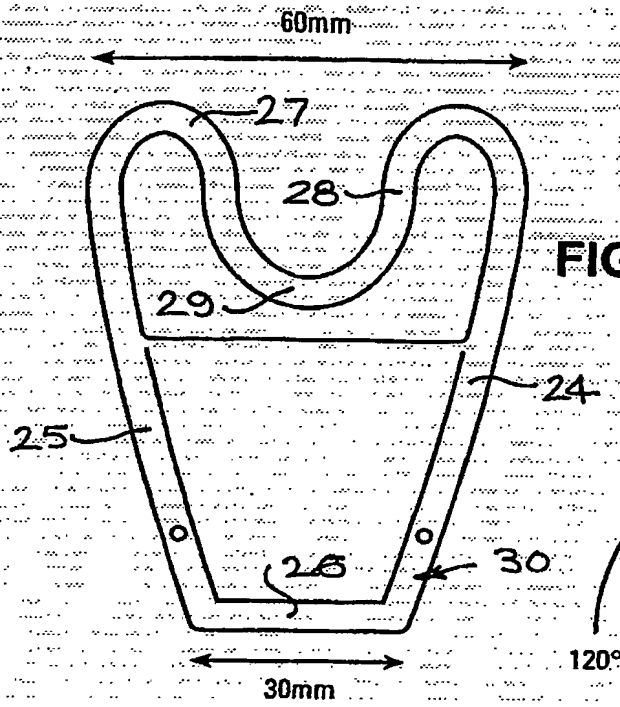


FIG 11

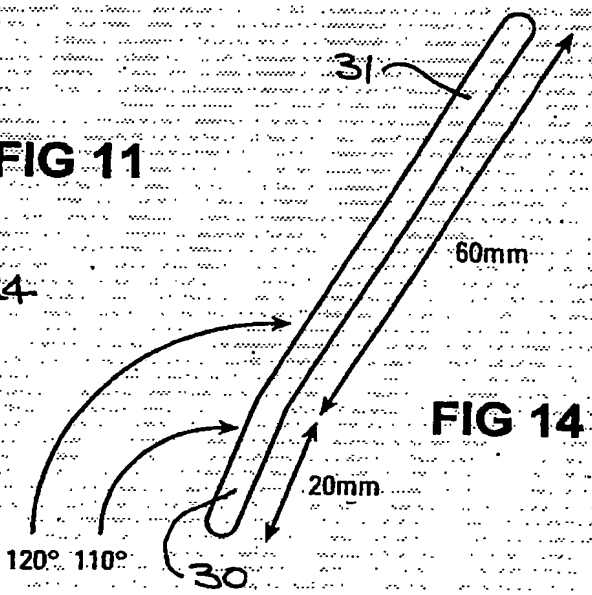


FIG 14

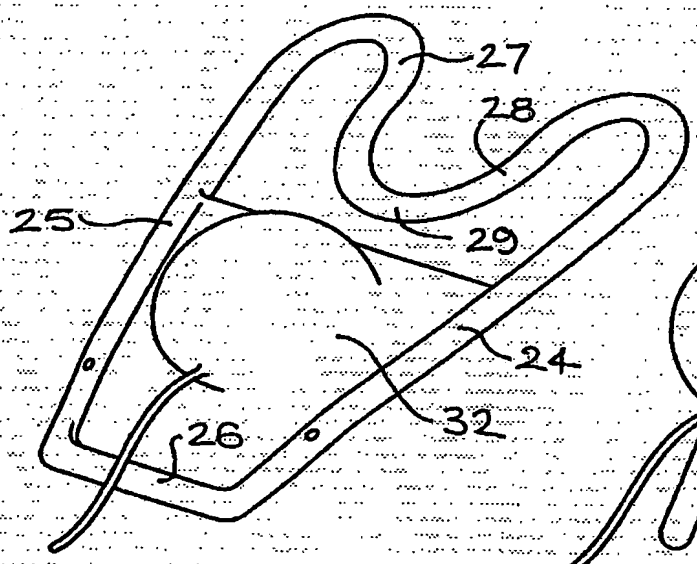


FIG 12

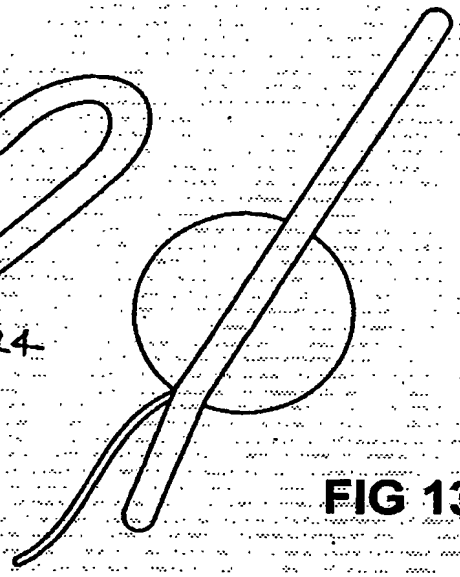

FIG 13

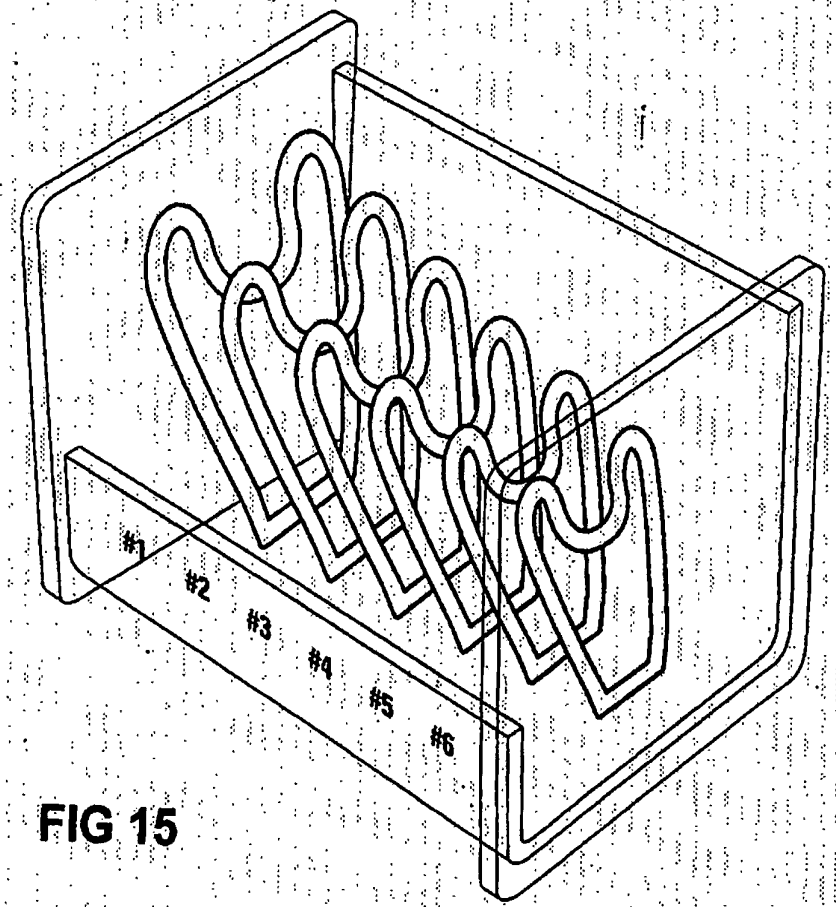


FIG 15